

EXHIBIT A

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01-CV-12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

)
) *United States of America ex rel. Ven-A-Care of the*
) *Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
) Civil Action No. 05-11084-PBS
)

**DEY DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER
SUPPORT OF THEIR MOTION *IN LIMINE* TO EXCLUDE FROM EVIDENCE
THE REPORTS AND TESTIMONY OF THEODORE R. MARMOR, PH.D.**

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") submit this reply memorandum of law in further support of their Motion to Exclude From Evidence the Reports and Testimony of Theodore R. Marmor, Ph.D.

PRELIMINARY STATEMENT

Plaintiff the United States and Plaintiff Relator Ven-A-Care of the Florida Keys, Inc. (collectively, "Plaintiffs") contend that Prof. Marmor's testimony will respond to what they characterize as the "government knowledge defense." Plaintiffs apparently use the phrase "government knowledge defense" as a code word for the overwhelming evidentiary record demonstrating that government officials and entities responsible for administering the Medicare and Medicaid programs understood throughout the relevant time period that published AWP did not reflect providers' actual final net costs to acquire drugs and deliberately chose to make reimbursement payments to providers that they knew were significantly higher than providers' net costs. Plaintiffs contend that, despite this evidence, Prof. Marmor will testify that the

government never formally “approved of” or “acquiesced in” Dey’s price reporting practices. For reasons Dey will address separately in its opposition to Plaintiffs’ Motion *In Limine* to Preclude Evidence of “Government Knowledge” (Docket No. 7132), the issue of whether the government formally approved of or acquiesced in Dey’s price reporting practices is not a correct test for Plaintiffs’ claims and Dey’s defenses in this action. Setting that issue aside, however, Prof. Marmor’s testimony and reports are inadmissible under Rule 702.

First, Prof. Marmor’s testimony will not assist the jury and indeed may effectively usurp the role of the court in instructing the jury on these issues. Plaintiffs contend that Prof. Marmor will assist the jury by explaining that government decision making is a complex process consisting of negotiation among various stakeholders with competing interests and that it is improper to consider governmental policies to be the result of logical choices by a unitary actor. Yet Prof. Marmor’s opinions will add no expertise to testimony from witnesses with firsthand knowledge concerning the implementation of the various reimbursement rates at issue, which evidence shows that these rates were the product of negotiations between various stakeholders with competing interests. The jury is more than capable of concluding whether this evidence demonstrates government “approval” or “acquiescence,” subject to proper instruction from the Court, without Prof. Marmor’s help.

Second, Prof. Marmor failed to follow his own methodologies, rendering his testimony inadmissible under *Daubert*. Prof. Marmor contends that a proper analysis of government policy making must take into account the internal workings of the governmental institutions responsible for decision and the behind-the-scenes negotiations between various individual stakeholders with competing interests. However, Plaintiffs concede that Prof. Marmor limited his review to “official pronouncements of government policy” and the formal avenues of

policy implementation, not the internal, behind-the-scenes operations and negotiations that Prof. Marmor claims a proper analysis would require. In fact, much this type of evidence was not available for Prof. Marmor to review, because of Plaintiffs' assertion of the deliberative process privilege. In other words, Professor Marmor failed to analyze evidence that is essential to his purported methodology. Indeed, it does not appear that Prof. Marmor applied any meaningful methodology at all. Instead, it appears he simply reviewed evidence cherry-picked for him by Plaintiffs' counsel, then drew the conclusions that Plaintiffs wished him to draw. His failure to rely on any consistent, reproducible methodology renders his testimony inadmissible under *Daubert*.

ARGUMENT

I. PROF. MARMOR WILL NOT ASSIST THE JURY

Under Rule 702 of the Federal Rules of Evidence, an expert will be allowed to testify only if “scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue...” “One of the criteria for the admission of expert testimony under Rule 702 is whether a lay person can be expected to decide the issue intelligently without an expert’s help.” *United States v. Seabagala*, 256 F.3d 59, 66 (1st Cir. 2001). When the jury can understand the matters on which an expert will opine through the factual record without the assistance of an expert, the expert’s testimony is properly excludable. *See id.* (affirming district court’s exclusion of proffered expert, noting that “common sense supports the district court’s determination that jurors would understand, without the aid of expert testimony, that an individual whose primary language is other than English might have difficulty comprehending bureaucratic forms.”)

Plaintiffs do not contend that Prof. Marmor’s standards for “approval” or “acquiescence” are anything more than simple dictionary definitions that could not just as easily

be presented to the jury by the Court (assuming they are applicable at all). Instead, Plaintiffs argue that Prof. Marmor's testimony will help the jury understand the complexities of government decision making. *See* Plaintiffs' Memorandum In Opposition to Dey Defendants' Motion *In Limine* to Exclude from Evidence the Reports and Testimony of Theodore R. Marmor, Ph.D. ("Opp. Memo") at 8. Specifically, Plaintiffs contend that Prof. Marmor will testify how government conduct and policies cannot be viewed as the decisions of a unitary actor, but rather must be viewed with the understanding that "'government' is a complicated organization with an array of constituent parts." *Id.* According to Plaintiffs, his testimony "will help the jury understand how [drug reimbursement] policy evolved over time and the difficulty of changing policy in such a complicated and contentious field."

However, Prof. Marmor has no expertise to add to testimony from fact witnesses with first hand knowledge of the circumstances surrounding the federal government's selection of Medicare reimbursement methodologies and the complex political negotiations involved in those decisions. For instance, Robert Berenson, who was acting deputy administrator of HCFA in the fall of 2000, testified at length at his deposition concerning HCFA's decision to stop using the DOJ AWP as a basis for Medicare reimbursement. *See* June 30, 2010 Declaration of Neil Merkl ("Merkl Decl."), Ex. 1 at 33:12-21; 183:22-191:03; 263:03-269:01. In particular, Mr. Berenson testified about CMS's interactions with Congress on the issue, and the political pressure exerted by the Congressional Black Caucus and the provider community. *See id.* at 183:22-191:03; 263:03-269:01. Kathleen Buto, who was the deputy director of the Center for Health Plans and Policies at HCFA during 1997 and 1998, testified about the Clinton administration's attempt to move Medicare reimbursement away from an AWP-based system and towards a system that reimbursed based on providers' actual acquisition costs and

Congress's rejection of that proposal. *See* Merkl Decl., Ex. 2 at 59:13-61:15; Ex. 3 at 376:01-381:10. Thomas Scully, who was the administrator for CMS during the first term of the Bush Administration, was a lobbyist in 1997 and 1998 who worked to oppose the Clinton Administration's proposal to move to an actual acquisition cost-based reimbursement system for Medicare. *See* Merkl Decl., Ex. 4 at 48:20-49:9, 50:8-13; 43:20-44:6. Mr. Scully also testified at length about the difficulties he faced as administrator of CMS in getting Congress to support changes to the reimbursement methodology:

Q: So the issue was not knowledge but it was generating the right political support to make these changes; right?

A: It's one thing to have the aging committee having a hearing and wave an OIG report, it's another thing to get 218 votes in the House and 60 votes in the Senate to fix it when the constituents – 218 votes in the House and 60 votes in the Senate to fix the reimbursement when you have constituents screaming and yelling that they don't want it changed. So it was a political issue.

Merkl Decl., Ex. 5 at 762:12-763:1.

The point Plaintiffs seek to establish through Prof. Marmor's testimony – that decision making by the federal government is a complex process that entails lots of separate stakeholders with separate interests and that policy changes cannot be implemented overnight – can be made through the testimony of these current and former government employees or the numerous other government officials with firsthand knowledge of the implementation of the reimbursement policies that form the basis for Plaintiffs' claims in this action. Prof. Marmor's purported "expertise" will add no value to such evidence.

It appears that Plaintiffs' real motive in calling Prof. Marmor testimony is not to aid the jury, but to use his testimony as a proxy to present portions of testimony from fact witnesses selected by Plaintiffs' counsel, while at the same time shielding those witnesses from cross-examination. Despite the numerous federal officials with firsthand knowledge of the

relevant policy changes upon which Prof. Marmor opines, Plaintiffs have named only one witness from CMS that they expect to call at trial. They apparently intend to rely almost exclusively on Prof. Marmor to present such evidence. This is an improper use of expert testimony. *See United States v. Tucker*, 345 F.3d 320, 330 (5th Cir. 2003) (affirming exclusion of expert testimony where expert testimony proffered by defendant “was nothing more than an attempt by [defendant] to testify by proxy, ... and thereby avoid taking the witness stand and undergoing rigorous cross-examination.”) If Plaintiffs wish to present evidence concerning the ins and outs of government decision making, they should put up witnesses with firsthand knowledge of the particular government policies at issue in this case and let them testify fully. Plaintiffs should not be permitted to filter such testimony through an expert to keep the jury from hearing the whole story through fact witnesses.

II. PROF. MARMOR FAILED TO FOLLOW HIS OWN METHODOLOGY

Plaintiffs do not dispute that Prof. Marmor reviewed only a small portion of the record – selected for him entirely by others – in coming up with his opinions. Nor do they contest that Prof. Marmor did not have access to a large body evidence that the United States withheld on the grounds of the “deliberative process privilege.” Indeed, they concede that his review was limited to “the public records by and through which governments implement policies” and “official pronouncement[s] of government policy” and that internal, pre-decisional deliberations of agencies and the individual understandings of responsible individuals “were simply not relevant to Dr. Marmor’s inquiry.” *See* Opp. Memo at 10. Yet this limitation on his analysis is directly at odds with the “Alison Models” that Prof. Marmor espouses as the basis for his analysis. Where an expert fails to follow his own methodology, his conclusions are not replicable and are therefore inadmissible. *See Smith v. Freightliner, LLC*, 239 F.R.D. 390, 393 (D. N.J. 2006) (“In this case, Mr. Barone did not adequately assess factors two and three of this

own methodology. ... A basic requirement under *Daubert* is that the methodology followed is capable of being replicated. Here the methodology was not followed by Mr. Barone and thus cannot be replicated.”)

In his report, Prof. Marmor is critical of the Alison Model I approach to analyzing governmental action, which he describes as “treat[ing] the government of the United States ... as if policymaking were the choice of an individual selecting a course of action among competing options according to clear purposes and evaluative criteria.” See June 20, 2008 Expert Report of Professor Theodore R. Marmor, PhD. (“Marmor Report”) at ¶ 14.¹ This approach is flawed, according to Prof. Marmor, because it

does not take into account that American government is in fact quite complex. What we call American government is, from another interpretive standpoint, a varied and loose association of large organizations with routines, standard operating procedures and subunits that can have quite distinctive--often competing--understandings of their purposes and practices.

Id. at ¶ 15. Instead, Prof. Marmor endorses Alison Models II and III. Alison Model II, according to Prof. Marmor “takes large scale government bodies and programs as the units of analysis. ... Accordingly, predictions proceed from the structure, programs, and past behavior of the organizations whose actions are the object of description, explanation, and evaluation.” *Id.* ¶ 16. Alison Model III’s

focus is why actions at any one time emerge from bargaining episodes among individual players in positions of differential authority, persuasiveness, and power. In such bargaining analyses, the issue is why actors in various roles within the government produced particular actions--the policy choices best understood as resultants. It emphasizes how these resultants emerge from the exercise of skill, power, and advantage in contexts constrained by what various actors regard as the rules of the game.

¹ A copy of the Marmor Report is attached to the March 10, 2010 Declaration of Neil Merkl (Docket No. 6971) at Ex. 3.

Id. at ¶ 17.

With their focus on the underlying institutions and actors behind government policy decisions, a Model II or Model III analysis must necessarily entail some consideration of the internal operation of those institutions and the knowledge, motives, and intentions of the those various actors. Yet, according to Plaintiffs' opposition, Prof. Marmor focused only on official government pronouncements and did not consider the type of internal agency evidence that would be critical for a Model II or Model III level analysis. According to Plaintiffs, Prof. Marmor concludes that the "government" must not have approved of or acquiesced in Dey's price reporting practices because the "government" did not issue some formal policy pronouncement saying so. In other words, Prof. Marmor's conclusion rests on the same Model I type of analysis – namely that the government policies can be understood as the rational choices of a single unitary actor – that he claims is the flaw underlying Dey's "government knowledge" arguments. Plaintiffs and Prof. Marmor cannot have it both ways. If it is improper to conclude that an absence of formal governmental action constitutes approval or acquiescence, it is equally improper to conclude that an absence of formal governmental action constitutes disapproval or an absence of acquiescence.

Prof. Marmor's failure to review documents and testimony withheld by the United States based on the "deliberative process privilege" is particularly at odds with the Model II and Model III analyses he espouses. This material would be essential to a Model II or Model III analysis as, by definition, it consists of "advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *Dept. of the Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001). Contrary to the picture Plaintiffs paint in their brief, the Special Master only determined that a small portion

of the “deliberative process” material was marginally relevant. Plaintiffs fail to mention that, shortly before the close of discovery, the United States voluntarily produced 1,600 pages worth of deliberative process documents it characterized as “released from privilege,” rather than submitting them to the Special Master for review. However, the United States did not begin producing these documents until well after Prof. Marmor issued his main report. Likewise, Plaintiffs do not mention that the Special Master overruled the United States’ deliberative process privilege objections to several questions posed at depositions of for current and former federal officials and directed those depositions to be reopened. Again, the continuation of these depositions did not occur until well after Prof. Marmor prepared his report. Thus, the implication in Plaintiffs’ brief that this material was properly withheld from Prof. Marmor because it was deemed to be irrelevant is wrong.

Indeed, Prof. Marmor does not appear to use any type of systematic, rigorous methodology at all. Apart from describing the Alison Models as interpretative “lenses” that give him “three different portraits” of the facts (*see* Moving Brief at 17), he fails to offer any insight into the methods by which he reached his conclusions at all. Likewise, Plaintiffs’ Opposition merely regurgitates the background portions of Prof. Marmor’s reports describing why the Alison Models are useful in analyzing government behavior, but makes no effort to establish *how* Prof. Marmor applied those models to reach his conclusion. *See* Opp. Memo at 12. Given that he did not properly follow the Alison Models he claims to be his methodology, and that it is unclear what methodology he did apply, his testimony and opinions are not admissible under *Daubert*.

CONCLUSION

For the foregoing reasons, as well as the reasons set forth in Dey's Memorandum of Law In Support of Its Motion *In Limine* to Exclude from Evidence the Reports and Testimony of Theodore Marmor, Ph.D., Dey respectfully requests that the Court grant Dey's motion to exclude the testimony of Prof. Marmor at trial, and to preclude the Plaintiffs from otherwise making use of, or relying upon, Prof. Marmor's opinions or testimony.

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Respectfully Submitted,

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